Niramai Health Analytix Private Limited
℅ Yolanda Smith
Consultant
Smith Associates
1468 Harvell Avenue
CROFTON MD 21114

March 10, 2022

Re: K212965
Trade/Device Name: Smile-100 System
Regulation Number: 21 CFR 884.2980
Regulation Name: Telethermographic System
Regulatory Class: Class I, reserved
Product Code: LHQ
Dated: January 31, 2022
Received: February 2, 2022

Dear Yolanda Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212965

Device Name
SMILE-100 System

Indications for Use *(Describe)*
SMILE-100 System is intended to review, measure and record skin temperature patterns and variations emitted from the human body. It is intended for use as adjunctive diagnostic imaging for thermally significant indications in the breast region. The significance of the value of these thermal patterns is determined by professional investigation. This device is intended for use by qualified healthcare personnel trained in its use. The system is not intended for absolute temperature measurements. The system is not intended to be used as a thermometry device.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary – K212965

5.1 Submitter

Niramai Health Analytix Private Limited,
Innova Pearl, Ground Floor,
No. 17, 5th Block, Koramangala Industrial Layout,
Koramangala, Bangalore - 560095,
Karnataka, India

Contact Person: Dr. Geetha Manjunath
Email id: contact@niramai.com

Date Prepared: 9 March 2022

5.2 Device Details

Trade Name	SMILE-100 System
Common or Usual Name	Telethermographic System
Classification Name	System, Telethermographic (Adjunctive Use)
Regulation Number	21 C.F.R. 884.2980
Device Class	Class I
Product Code	LHQ

5.3 Predicate Device Details

Product Name	Med-Hot Thermal Imaging Systems
Manufacturer	Med-Hot Thermal Imaging, Inc.
510(k) Number	K171928

5.4 Device Description

The SMILE-100 System is a breast thermography device with a visualization tool that helps a healthcare personnel to review, measure and analyze thermally significant indications in the breast region. It is intended to be used in the hospital, acute care settings, outpatient surgery, healthcare practitioner facilities or an environment where patient care is provided by qualified healthcare personnel.

SMILE-100 System consists of the following:

(i) An off-the-shelf FDA cleared thermal camera with its associated camera control software provided by the thermal camera vendor for capturing and viewing thermal images

(ii) An off the shelf laptop/desktop computer system with display, keyboard and mouse.

(iii) SMILE-100 Software for viewing thermal patterns in thermal images

The SMILE-100 Software takes thermal images captured using off-the-shelf FDA-cleared thermal camera and provides various visualization options in multiple customizable views/palettes and also generates a report with quantitative thermal parameters and annotated images. The Software supports two user roles (i) a thermographer or imaging technician role and (ii) Expert thermologist role. The imaging technician captures thermal images and uploads them to the cloud-hosted SMILE-100 Software which performs image quality checks and submits to Expert. The Expert can select a temperature threshold for the SMILE-100 Software to highlight areas with thermal activity above the threshold in thermal images. The software makes no estimation of the thermal threshold. The software makes no determination regarding what the thermal patterns or relative temperature values mean. Expert thermologist needs to infer the meaning of high thermal activity and other areas of interest based on his/her visual interpretation of those patterns and thermal values.

5.5 Indications for Use

SMILE-100 System is intended to review, measure and record skin temperature patterns and variations emitted from the human body. It is intended for use as adjunctive diagnostic imaging for thermally significant indications in the breast region. The significance of the value of these thermal patterns is determined by professional investigation. This device is intended for use by qualified healthcare personnel trained in its use. The system is not intended for absolute temperature measurements. The system is not intended to be used as a thermometry device.

5.6 Comparison of SMILE-100 System with the Predicate Device

Table 1: Indications for Use Statement Comparison		
SMILE-100 System	Predicate Device	Comment
SMILE-100 System is intended to review, measure and record skin temperature patterns and variations emitted from the human body. It is intended for use as adjunctive diagnostic imaging for thermally significant indications in the breast region. The significance of the value of these thermal patterns is determined by professional investigation. This device is intended for use by qualified healthcare personnel trained in its use. The system is not intended for absolute temperature measurements. The system is not intended to be used as a thermometry device.	The Med-Hot Thermal Imaging Systems are intended to review, measure and record skin temperature patterns and variations emitted from the human body. They are intended for use as adjunctive diagnostic imaging for thermally significant indications in the regions of the head and neck, breast, chest, abdomen, back and extremities. The significance of the value of these thermal patterns is determined by professional investigation. This device is intended for use by qualified technical personnel trained in its use.	Different The indications for use of both devices are the same except that the SMILE-100 System covers one anatomical site (breast) while the Predicate Device supports breast and other parts of the body.

Table 2: Predicate Product Comparison of Regulatory Parameters			
Parameters	SMILE-100 System	Med-Hot Thermal Imaging Systems	Equivalence
Product code	LHQ	LHQ	Same
Regulation No.	21 CFR 884.2980	21 CFR 884.2980	Same
Classification	Class I	Class I	Same

Regulation Name	Telethermographic System	Telethermographic System	Same

Table 3: Comparison of Technological characteristics			
Parameters	SMILE-100 System	Predicate Device	Equivalence
Principle of operation	Telethermography	Telethermography	Same
Method of Data Collection	Non-contact measurement of passive infrared emissions	Non-contact measurement of passive infrared emissions	Same
Temperature Measuring instrument	An infrared camera. FLIR A315, FLIR A310, FLIR E75, FLIR E76, FLIR Axxx series, FLIR Exx series (Ref K033967), Spectron IR's TyTron C-500 IR (Ref K032471), Infrared Cameras Inc.'s 9640P (Ref K073581)	An infrared camera. MAX 076 (FLIR A325sc) or MAX 307 (FLIR A655sc)	Similar Both devices use infrared cameras as the temperature measuring instruments. Though the camera model numbers are different, they have equivalent specifications (detailed below)
Table 3.a Technological Characteristics of Infrared/Thermal Camera			
Detector Type	Focal Plane Array (FPA), uncooled Microbolometer	FPA, Uncooled Microbolometer	Same
Thermal sensitivity	< 50 mK	< 50 mK	Same
Accuracy	±2°C or ±2% of reading	±2°C or ±2% of reading	Same
IR Resolution	Minimum 320 × 240 pixels	320 × 240 pixels	Same
Field of view	25°×18.8°	25°×18.8°	Same
Emissivity	from 0.01 to 1.0	from 0.01 to 1.0	Same

Table 3.b Technological Characteristics of the System			
Display Device	Laptop	Laptop	Same
Record thermal images to hard disk	Yes	Yes	Same
Infrastructure for analysis and data storage	Secure cloud server	Hard Disk	Different
Thermal Image Visualization Software Used	SMILE-100 Software	MedHot TotalVision Software	The two software's have similar characteristics as detailed in Table 3.c below
Table 3.c Technological Characteristics of Thermal Image Visualization Software			
Manual marking of regions that have high thermal activity	Yes	Yes	Similar
Input image quality check	Yes	No	Different
Temperature value display for every pixel	Yes	Yes	Same
Support for role-based access control	Yes	No	Different
Thermal Parameters generated in the output	Yes	Yes	Different Additional thermal parameters shown.
Compatibility with standard imaging format (DICOM)	Yes	No	Different

5.7 Performance Testing

The overall verification activities performed for SMILE-100 Software includes the following:

- Verification during Product Development
- Verification of SMILE-100 System Output Parameters
- Interoperability Testing with different Thermal Camera Models
- Comparison of the equivalence of temperature values between thermal camera and SMILE-100 Software

The following standards were followed in the development of the SMILE-100 System:

- ISO 14971: 2019 Medical Devices - Application of Risk Management to Medical Devices
- IEC 62304: 2015 Medical Device Software - Software Life Cycle Processes

5.8 Conclusion

The SMILE-100 System is a breast thermography device with a visualization tool. The SMILE-100 System is only an adjunctive diagnostic imaging modality. From the discussion above, it is determined that SMILE-100 System is substantially equivalent to the Predicate Device, and there are no new concerns of safety and efficacy. The device has also been described and tested to prove the same.